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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,506	04/12/2004	Carl G. Hellerqvist	22100-0202 (49530-299673)	3571
23370	7590	09/19/2007	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	
			MAIL DATE	DELIVERY MODE
			09/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,506	<b>Applicant(s)</b> HELLERQVIST ET AL.	
	<b>Examiner</b> Ruixiang Li	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 82, 85-89, 97, 99 and 102-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 82, 85-89 and 104 is/are allowed.
- 6) ☒ Claim(s) 97 and 105 is/are rejected.
- 7) ☒ Claim(s) 99, 102 and 103 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/20/2007 has been entered.

Claims 82, 85-89, 97, 99, and 102-105 are pending and currently under consideration.

### **Withdrawn Objections and/or Rejections**

The rejection of claim 97 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amended claim.

The rejection of claims 82, 83, 85-89, 98-100, 102-105 under 35 U.S.C. 112, first paragraph for scope of enablement is withdrawn in view of amended and canceled claims, as well as Applicants' argument regarding the GBS toxin receptor that has at least about 86% identity to SEQ ID NO: 87.

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The rejection of claims 82, 83, 85-89, 97-100, 102-104 under 35 U.S.C. 112, first paragraph for written description is withdrawn in view of amended claims and canceled claims.

### **Claim Rejections Under 35 U.S.C. §112, 1<sup>st</sup> Paragraph**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claim 97 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody or a fragment thereof that binds the mammalian GBS toxin receptors recited in the claims, does not reasonably provide enablement for an isolated antibody or a fragment thereof recited in claim 97. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claim.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

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Claim 97 is drawn to a composition comprising a reagent for detection of GBS toxin receptor, wherein the reagent is an isolated antibody or a fragment thereof. There are no structural and functional limitations for the antibody or a fragment thereof. It is well-known in the art only an antibody that is produced using a GBS toxin receptor or its immunogenic polypeptide fragment can be used to detect the GBS toxin receptor. An antibody that does not have a binding affinity for the GBS toxin receptor cannot be used to detect the GBS toxin receptor. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claim.

#### Response to Applicants' argument

Applicants argue that claim 97 and its dependent claims specify that the reagent for the detection of the GBS toxin receptor is an isolated antibody or a fragment thereof. This is not persuasive because the claim does not require that the recited antibody binds to the GBS toxin receptor.

(iii). Claim 105 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

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Claim 105 is drawn to a composition comprising an antibody or a fragment thereof that recognizes a mammalian GBS toxin receptor, wherein the composition is isolated from an animal or a human. However, there is no adequate description for such a composition isolated from a human. One skilled in the art would not recognize from the disclosure that the applicant was in possession of such a composition.

Applicants argue that support for claim 105 is found throughout the specification, as filed. This is not persuasive because there is no support for the isolated composition isolated from a *human* in the specification and Applicants fail to point out the support for such a composition in the specification.

### **Claim Objections**

Claims 99, 102, and 103 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Conclusion**

Claims 82, 85-89, and 104 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00

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pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.  
Primary Examiner  
September 15, 2007

RUIXIANG LI, PH.D.  
PRIMARY EXAMINER